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EXAMINER	
LEROUX, ETIENNE PIERRE	

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DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,705	CLASSEN, JOHN BARTHELOW	
	Examiner	Art Unit	
	Etienne P LeRoux	2161	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (5) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is FINAL. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-200* is/are pending in the application.

4a) Of the above claim(s) *1-32 and 85-200* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) ___ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Application/Control Number: 10/081,705
Art Unit: 2161

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121: Applicant is required to select one of the following patentably distinct inventions for first action examination on the merits:

I. Claims 1-32, drawn to a system for creating and using product data, classified in class 707, subclass 3.

II Claims 33-84 drawn to a method of commercialization of essential adverse event information of a product, classified in class 705, subclass 10.

IIIa Claims 85, 86, 95-98, 103, 105, 107, 109, 111, 113, 115, 117, 119, 121, 123, 125, 127, 129, 131, 133, 140-142, 144-146, 148, 150-152, 154, 156-160 drawn to a method of establishing at least one new use for a product/device, class 705, subclass 26.

IIIb Claims 85, 87-94, 99-102, 104, 106, 108, 110, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134-139, 143, 147, 149, 153, 155, drawn to a method for commercialization of a new use for a product/device, classified in class 707, subclass 104.1.

IV Claims 161-198, drawn to a method for establishing a product safety data sheet, classified in class 283, subclass 81.

V Claims 199-200, drawn to a method for marketing/packaging a device, classified in class 53, subclass 411.

Inventions I, II, IIIa, IIIb, IV and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, per MPEP § 806.05(d), the following inventions have separate utility as noted below:

Invention I has separate utility because the system can be used to analyze a product to produce a specification.

Invention II has separate utility because the method can be used to market hazardous information.

Invention IIIa has separate utility because the method can be used to analyze a product in commercial production to derive a new use for the product.

Invention IIIb has separate utility because the method can be used to market a new use for a product.

Invention IV has separate utility because the method can be used to produce a material safety data sheet which can then be commercialized.

Invention V has separate utility because the method can be used to provide information on a package of a product in order to improve the saleability of the product.

Should applicant traverse on the ground that the subcombinations are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the subcombinations to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). A telephone call was made to Ms Evelyn McConathy on 9/21/2004 to request an oral election. Claims 33-84 were elected, without traverse, for initial examination on the merits.

Claim Status:

Claims 33-84 are pending. Claims 1-32 and 85-200 have been withdrawn without traverse.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 33 recites "analyzing the adverse event data to identify new essential adverse events associated with the product or device." The skilled artisan would not be able to make and

use the invention because the manner and process of making new essential adverse events is not clearly and concisely described in the specification. The most relevant information from the specification is the following:

> [0068] As indicated by step 26' in FIGS. 5 and 6, at the request any of these persons or entities or on its own behalf, the owner or licensee of server, 14, 114 or 214 accesses and retrieves raw adverse event product data from adverse event database(s) 12. At step 28' the server analyzes the retrieved data to identify new essential adverse events regarding a product or device, to conduct cost/benefit analyses related to the newly discovered essential adverse events or to perform any other desired analysis of the raw data. At step 30' the server creates one or more proprietary essential adverse information databases that are stored in essential adverse information storage device 22. At step 32' in FIG. 5 the licensee or owner or owner of server 14, 114 or 214 commercializes the essential adverse event information in essential adverse information storage device 22 by selling or licensing the proprietary information to a third party. The third party communicates with system 10, 110 or 210 through user computer 24. The user computer interfaces with user interface 20 to make requests for information to and to receive information from the processor 18 of server 14, 114 or 214. Interpretation of the received information may be performed by the third party, an independent contractor, the owners or licensees of server 14, 114 or 214 or the owner(s) or licensees of the essential adverse event database(s) 12.

The skilled artisan would be confused by the above description of the invention. It appears that the process of identifying a new essential adverse event comprises the following: 1) analysis of cost/benefit, 2) any other desired analysis of the raw data. In particular, the method steps required to perform the cost/benefit analysis are not provided. A cost/benefit analysis is particular to a particular field, especially in the medical field where possible death of a patient must be included in cost. To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. The above description

includes "any other analysis of the raw data" which demonstrates that the applicant did not have possession of the invention at the time of filing instant application.

Claim 33 recites "wherein the creating step comprises analyzing data from the at least one adverse event data source to identify at least one new useful characteristic or use for the product or device responsive." The skilled artisan would not be able to make and use the invention because the manner and process of making a new useful characteristic or use for the product or device is not clearly and concisely described in the specification.

Claim 44 "recites wherein commercializing further comprises formatting the data relating to at least one new adverse event associated with exposure to, or use of the product or device, or documenting same, such that a manufacturer or distributor of the product or device must inform consumers, users or individuals responsible for the user, physicians or prescribers about at least one new adverse event associated with exposure to or use of the product or device." The skilled artisan would not be able to make and use the invention because the manner and process of making a manufacturer or distributor of the product or device inform consumers is not clearly and concisely described in the specification.

Claim 68 recites "wherein at least one new adverse event is based upon neither a drug interaction, nor a chronic immune mediated disorder." The skilled artisan would not be able to make and use the invention because the manner and process of making a new adverse event based upon neither a drug interaction nor a chronic immune mediated disorder is not clearly and concisely described in the specification.

Claim 76 recites "using the method to develop at least one essential proprietary new method of screening a product or device for safety." The skilled artisan would not be able to

make and use the invention because the manner and process of making a new method of screening is not clearly and concisely described in the specification.

Claims 34-43, 45-67, 69-75 and 77-84 are rejected for being dependent from a rejected base claim.

Art Rejected Precluded

Claims 44, 68 and 76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. No art rejection is provided in this first action on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33-36, 38-40, 48-51, 56, 57 and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by Pub No US 2001/0001144 issued to Kapp (hereafter Kapp).

Claim 33 and 76:

Kapp discloses:

- accessing at least one adverse event data source [Therapy Coordinator module 128 provides a drug interaction module 150, par 59, Fig 5] that stores adverse event data associated with a product or device
- analyzing [Therapy Coordinator module 128 provides a drug interaction module 150, par 59, Fig 5] the adverse event data to identify new essential adverse events associated with the product or device
- creating at least one essential adverse event information database [database is inherent because a DUE report indicating utilization of a drug can be generated, par 58] wherein the creating step comprises analyzing data from the at least one adverse event data source to identify at least one new useful characteristic or use for the product or device responsive to identification of at least one new essential adverse event associated with the product or device, wherein the creating step further comprises storing essential adverse event information, and wherein the adverse event information includes the at least one new use or characteristic; and
- commercializing essential adverse event information stored at the essential adverse event information database [pharmacy drug management system may be used at any location in the world, par 58]

Claim 34:

Kapp discloses wherein accessing further comprises accessing the at least one adverse event data source comprising raw data from a plurality of different adverse events [par 9].

Claim 35:

Kapp discloses wherein accessing further comprises accessing data from the at least one adverse event data source comprising adverse event information regarding exposure to or use of the product or device [par 9].

Claim 36:

Kapp discloses wherein accessing further comprises accessing the at least one adverse event data source further comprising information regarding adverse events selected from at least two categories selected from the group consisting of death, illness, hospitalization, missed work, medical costs, abnormal laboratory results and surgeries [par 5].

Claim 38:

Kapp discloses further accessing at least one data source comprising information relating to raw commercial or sales data [par 6].

Claim 39:

Kapp discloses further comprising providing the at least one adverse event data source comprising adverse event data gathered from at least 5000 subjects [par 6].

Claim 40:

Kapp discloses providing the at least one adverse event data source comprising information regarding amount of use of the product or device or duration of exposure to the product or device by each subject [par 10].

Claim 48:

Kapp discloses the essential adverse information is proprietary [Fig 8A, 196]

Claim 49:

Kapp discloses a proprietary product or device [Fig 8B, step 204]

Claims 50, 51, 56 and 57:

Kapp discloses the product is medical [Fig 8B, step 204].

Claim 64:

Kapp discloses the product is commercially available [par 3]

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37, 43, 45, 65, 69, 73-75, 77, 79 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapp.

Claims 37, 65, 69, 73, 74, 79 and 80:

Kapp discloses the elements of claim 33 as noted above.

Kapp fails to disclose accessing at least one data source comprising information relating to patents and patent applications.

Official Notice is taken that patents and patent applications are a well-known and expected data source to one of ordinary skill in the art because patents and patent applications include novel and non-obvious sources of data. The ordinarily skilled artisan would have been motivated to improve Kapp's invention by considering data sources included in patents and patent applications for the purpose of ascertaining the current state of the art.

Claim 77:

Kapp discloses using the method to develop at least one essential proprietary new method of screening a product or device for safety [par 10]

Claims 43 and 45:

Kapp discloses the elements of claim 33 as noted above.

Kapp fails to disclose wherein commercializing further comprises protecting the intellectual property interest in the newly identified product information

Official Notice is taken that wherein commercializing further comprises protecting the intellectual property interest in the newly identified product information is well-known and expected in the art because an inventor knows that a patent provides intellectual property protection. The ordinarily skilled artisan would have been motivated to improve the invention of Kapp by seeking patent protection for the purpose of obtaining exclusive use of the invention for a 20 year term.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kapp in view of US Pat No 6,323,242 issued to Mueller (hereafter Mueller) as best examiner is able to ascertain.

Claim 41:

Kapp discloses the elements of claims 33 and 39 as noted above.

Kapp fails to disclose providing the at least one adverse event data source comprising information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than one year.

Mueller discloses providing the at least one adverse event data source comprising information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than ten years [col 17, lines 10-40].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kapp to include providing the at least one adverse event data source comprising information regarding product post-exposure adverse event data, which is recorded in selected time increments, ranging from less than one hour to more than one year as taught by Mueller for the purpose of monitoring the wearoff of the drug based on the tolerance level of the patient [col 17, lines 10-40]. The ordinarily skilled artisan would have been motivated to improve Kapp's invention per the above so that effects of medication can be ascertained while treating a patient who had a long history of substance abuse [col 17, lines 10-40].

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kapp in view of Pub No US 2002/0082930 issued to Park (hereafter Park), as best examiner is able to ascertain.

Claim 42:

Kapp discloses the elements of claim 33 as noted above.

Kapp fails to disclose wherein commercializing further comprises selling, leasing or licensing the newly identified product information.

Park discloses wherein commercializing further comprises selling, leasing or licensing the newly identified product information [par 128].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kapp to include wherein commercializing further comprises selling, leasing or licensing the newly identified product information as taught by Park for the purpose of providing assistance to the vendor to sell the product [par 128]. The ordinarily skilled artisan would have been motivated to improve the invention of Kapp by including correct and useful information such that the consumer is able to determine if the product meets his/her needs [par 128].

Claims 46, 47, 66, 67 and 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapp in view of US Pat No 5,181,394 issued to Schea et al (hereafter Schea) as best examiner is able to ascertain.

Claims 46, 47, 66, 81, 82 and 83:

Kapp discloses the elements of claims 33, 64 and 49 as noted above.

Kapp fails to disclose identifying the at least one new use of the product or device as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device. Schea

discloses identifying the at least one new use of the product or device as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device [col 1, line 40-col 2, line 6]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kapp to include identifying the at least one new use of the product or device as a restricted use in at least one population subgroup when there is observed to be a high risk of at least one adverse event associated with exposure to or use of the product or device as taught by Schea for the purpose of identifying a potential risk that the recipient may develop adverse immunological responses [col 1, line 68]. The ordinarily skilled artisan would have been motivated to improve the invention of Kapp per the above for the purpose of identifying the effects of extreme temperatures on biologically active materials [col 1, lines 40-45].

Claim 67:

Kapp discloses wherein at least one new adverse event comprises a drug interaction [Fig 8A, step 150]

Claims 52 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapp in view of US Pat No 6,696,924 issued to Socinski (hereafter Socinski) as best examiner is able to ascertain.

Claims 52 and 53:

Kapp discloses the elements of claims 50 and 51 as noted above. Kapp fails to disclose wherein the medical product is a generic drug. Socinski discloses wherein the medical product is a generic drug [col 3, lines 35-45]. It would have been obvious to one of ordinary skill in the art

at the time the invention was made to modify Kapp to include wherein the medical product is a generic drug as taught by Socinski for the purpose of providing a hand-held computer including a database of drug companies and their products [col 3, lines 35-40]. The ordinarily skilled artisan would have been motivated to improve the invention of Kapp by including a generic drug in a hand-held computer database such that the patient has an easily accessible schedule which alerts a user to scheduled medications [abstract].

Claims 54, 55, 58, 59, 70-72 and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapp in view of Pub No US 2003/0004965 issued to Farmer et al (hereafter Farmer), as best examiner is able to ascertain.

Claims 54, 55, 58, 59, 70, 71 and 72:

Kapp discloses the elements of claims 33, 49 and 69 as noted above. Kapp fails to disclose wherein the product is non-medical. Farmer discloses wherein the product is non-medical [par 10]. It would have been obvious to one of ordinary skill in the at the time the invention was made to modify Kapp to include wherein the product is non-medical as taught by Farmer for the purpose of improving the invention of Kapp to include non-medical product information because including chemical products improves the commercialization possibilities of the database.

Claim 75:

Kapp discloses the elements of claims 33 and 70 as noted above. Kapp fails to disclose further comprising using the method to produce lower costs for development of the product or device, or quicker time to market, or an expected higher return for development costs associated

with the product or device, or any combination thereof. Official Notice is taken that further comprising using the method to produce lower costs for development of the product or device, or quicker time to market, or an expected higher return for development costs associated with the product or device, or any combination thereof is expected and well-known in the art because the above benefits are a direct result of obtaining patent protection.

Claim 78:

Kapp discloses using the method to develop at least one essential proprietary new method of screening a product or device for safety [par 10]

Claims 60, 62, 63 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kapp in view of US Pat No 6,715,796 issued to Foote et al (hereafter Foote), as best examiner is able to ascertain.

Claims 60, 62, 63 and 84:

Kapp discloses the elements of claim 33 as noted above. Kapp fails to disclose labeling notifying a user of at least one new essential adverse event for the product or device. Foote discloses labeling notifying a user of at least one new essential adverse event for the product or device [abstract]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kapp to include labeling notifying a user of at least one new essential adverse event for the product or device as taught by Foote for the purpose of providing instructions regarding usage of the drug [col 1, lines 20-35].

Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kapp and Schea and further in view of Pub No US 2003/0004965 issued to Farmer et al (hereafter Farmer) as best examiner is able to ascertain.

Claim 61:

The combination of Kapp and Schea discloses the elements of claim 49 as noted above. The combination of Kapp and Schea fails to disclose labeling notifying a user of at least one new essential adverse event for the product or device. Foote discloses labeling notifying a user of at least one new essential adverse event for the product or device [abstract]. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Kapp and Schea to include labeling notifying a user of at least one new essential adverse event for the product or device as taught by Foote for the purpose of providing instructions regarding usage of the drug [col 1, lines 20-35].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etienne LeRoux whose telephone number is ~~(703) 305-0620~~ (571) 272-4022. The examiner can normally be reached on Monday – Friday from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Safet Metjahic, can be reached on (703) 308-1436.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

Patent related correspondence can be forwarded via the following FAX number (703) 872-9306

Etienne LeRoux

9/30/2004

12/29/2005